

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION,)	
)	
Plaintiff,)	
v.)	Civil Action No. 97-550 (SLR)
)	
MEDTRONIC VASCULAR, INC., et al.,)	
)	
Defendants.)	
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)	
MEDTRONIC VASCULAR, INC.,)	
)	
Plaintiff,)	Civil Action No. 97-700 (SLR)
v.)	
)	
CORDIS CORPORATION, et al.,)	
)	
Defendants.)	

**MEDTRONIC VASCULAR INC.'S COMBINED REPLY BRIEF
IN SUPPORT OF ITS MOTION FOR JUDGMENT AS A MATTER
OF LAW ON CORDIS CORPORATION'S PATENT
INFRINGEMENT CLAIMS AND ITS MOTION FOR A NEW TRIAL**

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INTRODUCTION

The most notable feature of Cordis' combined answering brief (D.I. 1407) to AVE's JMOL and New Trial motions is what is not there – responses to the key arguments raised by AVE (D.I. 1397, 1398).

Cordis does not dispute that the Federal Circuit held that a stent wall with a “100% variation” in thickness could under no circumstances be deemed to meet the “substantially uniform thickness” limitation. Nor does Cordis dispute that a variation equal to or greater than two times in thickness constitutes a 100% variation in thickness. Instead, it presents a misdirection, arguing that variations in thickness only matter if they start from a “nominal” thickness and go “up” to twice as thick as the “nominal” thickness – a theory that Cordis thought was so sound that its experts never adopted it and Cordis chose to affirmatively argue it for the *first time during its closing arguments*.

The non-infringement issue is ripe for decision as a matter of law. Neither party disputes the structure of AVE's stents. The issue is whether Cordis's newly-minted construction of the “substantially uniform thickness” limitation is correct. In light of the Federal Circuit's decision in this case, Cordis's construction cannot stand and AVE's motion for judgment as a matter of law should be granted.

A new trial should also be granted. Cordis' misdirection undoubtedly confused the jury. In addition, Cordis does not dispute that it presented several arguments to the jury that were irrelevant, prejudicial, and made for the purpose of eliciting a verdict based upon emotion, not the facts. Instead, it just ignores certain of its arguments (such as, that the jury should “honor Dr. Palmaz” while pointing to the expiration date of the '762 patent) and quibbles about whether other irrelevant arguments were supported by evidence (which they were not).

ARGUMENT

I. AVE DOES NOT INFRINGE THE '762 AND '984 PATENTS AND JMOL SHOULD BE GRANTED

A. The Structure Of The AVE Stents Is Not In Dispute

Lost in Cordis's claim that it presented “overwhelming evidence” of infringement in support of the verdict is that there is no dispute as to the material facts – *i.e.*, the structure of the AVE stents. Cordis agrees, stating that “the structure of AVE's stents was undisputed at trial” (D.I. 1407 at 3).

The “thickness” of the stent wall is defined as “the distance between the outer point that intersects the wall surface and the corresponding inner point that intersects a similar imaginary cylindrical surface on the inside of the tubular member.” *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1362 (Fed. Cir. 2003). When viewed along the length of each individual AVE stent element, the thickness of the stent wall varies from thinner (near one end) to more than twice as thick (along the majority of its length) to thinner again (near the other end) (D.I. 1389, 3/9/05 Tr. at 1110:2-1111:5). Cordis agrees. It argued to the jury that the thickness at the ends of the stents varies:

Well, there is – I mean, *there is a variation here at the end* [of the AVE stents], just like there is a variation here and here and here and here and here, but it goes downward, it’s a negative deviation. It doesn’t go down a hundred percent. If it went down a hundred percent, there wouldn’t be any stent... You can’t have a hundred percent deviation.

(D.I. 1391, 3/11/05 Tr. at 1766:20-1767:10) (Emphasis in the quoted material is added unless otherwise noted.). Indeed, the figure shown on page sixteen of Cordis’s answering brief illustrates the variation.

In short, the sole issue for this Court to decide on AVE’s JMOL motion involves Cordis’ improper attempt to abrogate the Court and Federal Circuit’s construction of the “substantially uniform thickness” limitation – an issue of law. As a result, there are no factual disputes that would preclude entry of judgment of non-infringement. *Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, 163 F. Supp. 2d 426, 441 (D. Del. 2001); *see also Johnson Worldwide Assoc., Inc. v. Zebco Corp.*, 175 F.3d 985, 988 (Fed. Cir. 1999).

B. Cordis Misapplies The Federal Circuit Construction Of The “Substantially Uniform Thickness” Limitation

1. Cordis Improperly Focuses On Cross-Section Of The AVE Starting Material, Not On The “Walls” Of The Stent

Cordis’s rationale for why AVE’s variably thick stents have “walls” of a “substantially uniform thickness” is summed up in one answer by Dr. Collins, Cordis’s expert (Tr. at 513:7-17 (cited in D.I. 1407 at 6)):

A. In measuring the thickness, the question is: What are you measuring? You’re measuring the thickness of the strut, and that the strut is the

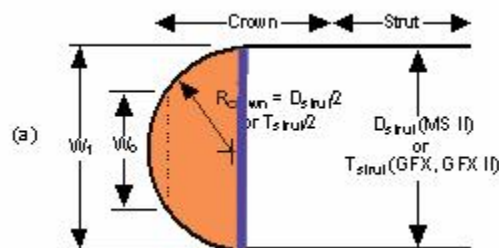
structural element. So you want to measure the thickness of the cross-section of the structural element.

This “structural element” test is wrong for a number of reasons.

First, Cordis’s cross-section approach is inconsistent with the Federal Circuit’s construction of the “thickness” limitation of the claim. The uniformity of a “cross-section” of a “structural element” is different from the “thickness” along the length of the wall of a stent, on which the Federal Circuit focused. *Cordis*, 339 F.3d at 1360. The Federal Circuit also correctly defined the term “thickness” by specifying the dimension to which this claim term refers. It held that the wall thickness of a tubular member is defined by the distance between a series of imaginary circles *along the length of the stent*. *Id.* at 1362; (*see also* D.I. 1389, 3/9/05 Tr. at 1101:13-1102:20). The “thickness of the wall” is “equal” to the distance between imaginary circles along the inner and outer surfaces of the stent. *Cordis*, 339 F.3d at 1362. Significantly, the Federal Circuit did not present this analysis as a “methodology” for measuring the stent. Rather, the analysis was presented as part of the Federal Circuit’s claim construction; and was included to further explain the meaning of the “thickness” term found in the “substantially uniform thickness” limitation. In short, the Federal Circuit’s construction of “thickness” was not one *example* of how to define the thickness of a wall, it is the construction of the term.

When the Federal Circuit’s construction is applied, the distance between respective circles in the center of each AVE sinusoidal ring element is more than twice as much as the distance between respective circles as one nears either end of the sinusoidal ring (D.I. 1389, 3/9/05 Tr. at 1110:18-1111:5; 1122:6-15). This was not disputed at trial, nor does Cordis dispute it now. If these imaginary rings are passed along the AVE stent elements from end to end, they show a substantial variation in thickness – of more than 100% – as one passes from either end of each ring along the stent wall.

Cordis’s “structural element” test ignores the thickness of the stent wall along the first and last portions of that wall as demonstrated below:



Cordis's own expert, Dr. Buller, unequivocally testified that the ends of the stent are included in the "wall") (D.I. 1388, 3/8/05 Tr. at 915:19-916:18):

Q. . . [W]here is the wall, the wall that you look at to measure substantially uniform thickness? *Does it run from end to end of the stent?*

A. *All of the metal is the wall of the stent. The metal is the wall of the stent.*

Because Cordis was permitted to propose a definition of wall thickness that effectively asked the jury to disregard those portions of the stent wall that are of substantially different thickness than the rest, Cordis was allowed to successfully rewrite the claims.

Second, the "structural element" test does not make sense in light of the intrinsic evidence. Dr. Palmaz's woven wire design, shown in Figure 1 of the '665 patent, does not have a "wall" with a "substantially uniform thickness" at least because of the overlapping wires (D.I. 1407 at 15). However, under the "structural element" test as proposed, even Dr. Palmaz's woven-wire embodiment would have uniform thickness because the cross-sections of the "structural elements" are uniform.

Third, the "structural element" test improperly focuses on the stents' starting material – *i.e.*, the "bent wire." But according to the Federal Circuit, the starting material is irrelevant to the claims. *Cordis*, 339 F.3d at 1357 ("[W]e decline to superimpose a process limitation on the product claims at issue."). The relevant inquiry is whether the "wall" of the final stent product has a "substantially uniform thickness."

2. Cordis Relies On Revisionist History To Rewrite The 100% Variation Language In The Court's Jury Instructions

Cordis's final argument in support of infringement is that, even though the ends of the AVE stent vary in thickness, the variation is not a 100 percent variation. Cordis presents two reasons in support.

First, it argues that, even assuming that some portions of the AVE stents are twice as thick as others, there is not a 100 percent variation because it is not possible to have a 100 percent deviation from a stent's "nominal" thickness. Second, it argues that the AVE stents are uniform along at least 98 percent of the stent. Both arguments are misdirections.

a. Cordis's Construction Is Inconsistent With The Federal Circuit

As explained in detail in AVE's JMOL and New Trial briefs, the Federal Circuit equated a 100 percent variation in wall thickness with a wall that is twice as thick in some areas as in others. *Cordis never disputes this point.* That should end the inquiry. There is no dispute that the alleged wall of each AVE stent has a portion near the middle of its length that is twice as thick as the portions of the wall near the ends of its length.¹

Aside from being contrary to the Federal Circuit opinion, Cordis's "nominal" thickness defies common sense. Taking Cordis's theory to the extreme, this obviously non-uniform strut (shown in cut-away form) would be substantially uniformly thick.

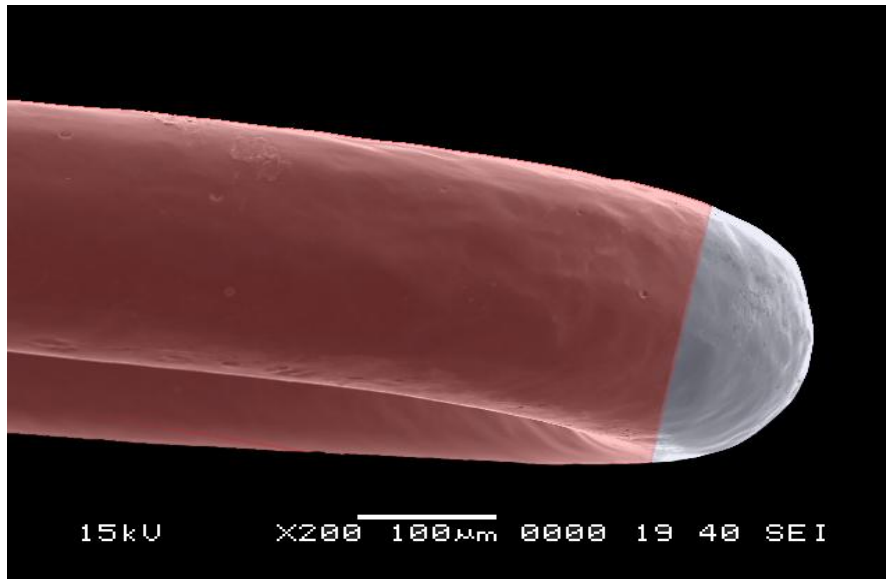


Assume this strut is formed from one piece of material and comprises one side of a slot. Since the portions highlighted in red constitute more than 50%, Cordis would apparently consider this to be the

¹

Cordis contends that this is the same issue that went to this Court and the Federal Circuit after the first trial. Cordis is wrong. As AVE stated in its JMOL reply brief filed May 11, 2001, "Cordis' discussion of the evidence submitted at trial is irrelevant for purposes of this motion – it relates solely to the thickness of the AVE stent struts along their lengths (D.I. 1092 at 16-17). With respect to the only material fact – *i.e.*, the cross-sectional dimension of the AVE struts - there is no dispute. The struts vary in cross-sectional thickness by more than .001 inch." (D.I. 1397 at 6). AVE specifically distinguished the argument appealed to this Court and the Federal Circuit as being limited to the strut portion of the stent and analyzing the variation in thickness in a circumferential direction. The Federal Circuit rejected this argument, holding that the thickness must be analyzed along the length of the stent. *Cordis*, 339 F.3d at 1362. The Federal Circuit construed the claim term "thickness" in a manner that excluded the lateral (side-to-side) circumferential variation of the struts discussed in the parties' briefs. *Id.*

“nominal” width of this structural element. Since the portions of the strut highlighted in blue represent a “negative” deviation off the “nominal” (one which tapers and one which abruptly goes to a thickness less than half of the red portions), Cordis would disregard the blue portions of the stent. This is not an extreme example – it is the basis for Cordis’s proposed claim construction and its entire infringement case was premised on convincing the jury to ignore the portions of AVE’s stent wall that do, in fact, vary substantially in thickness.



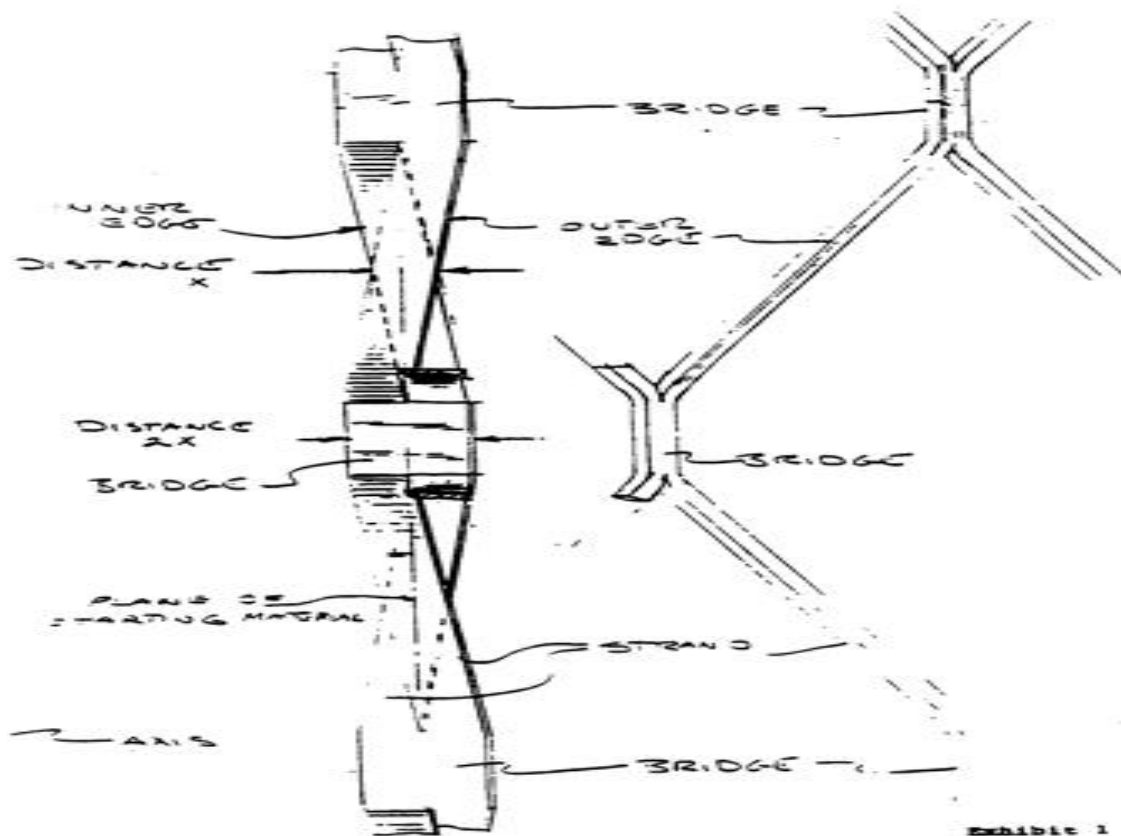
Cordis’s position also makes no sense in light of the ‘762 reexamination file history. During the reexamination, Cordis’s expert, Dr. Andros, distinguished the Ersek prior art patent based upon it having a thickness that varies by a factor of at least two (PX-13 at PWRAP 003079 SUB).

The Ersek fixation sleeve does not have a substantially uniform wall thickness, nor is it thin walled. The expanded metal sleeve is *twice as thick in some areas as in others*, and the thickness of the wall varies throughout.

Cordis explained that the reason for this variation is that the bonds and bridge areas of Ersek protrude inwardly and outwardly:

[I]n the first diameter configuration [of the Ersek sleeve], the wall of sleeve 16 is of varying thickness because the strands of the sleeve have twisted out of the plane of the starting material. Moreover, *the bonds or bridges at the junctions of the strands protrude inwardly and outwardly of the plane of the starting material*, and as a result the Ersek sleeve 16 has a non-uniform wall of varying thickness.

Nowhere in these exchanges does Cordis mention that Ersek has a “nominal” thickness, or that the “nominal” thickness plays any part in determining whether there is a 100 percent variation. Indeed, the Ersek stent that Cordis described to the PTO² has no “nominal” thickness. As seen in the diagram that Dr. Andros provided to the PTO, reproduced below, the stent surface rises and falls in a generally sinusoidal fashion. In fact, if one were to assume the “nominal” thickness was the “most common” thickness, then the bridges would actually represent the nominal thickness. The surface at the bridges, distance $2x$, is obviously much longer than the surface at “distance x .” So the thickness actually decreased from the nominal. Therefore, as presented to the PTO, it was Cordis’s theory that the Ersek stent had a “negative” deviation of 100%.



²

AVE does not agree with Cordis that the Ersek reference teaches a “double thickness” or 100% variation. However, for purposes of prosecution history estoppel, it is only important that this was the patentee’s position.

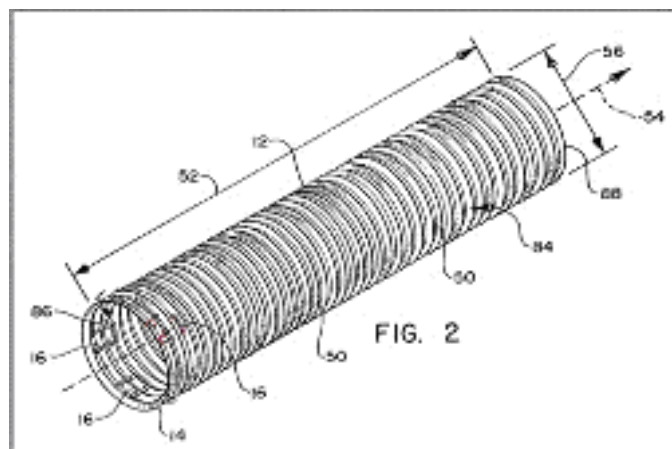
Dr. Andros characterized this variation as leading to an “expanded metal sleeve [that] is twice as thick in some areas as in others” (PX-13 at PWRAP 003079 SUB); and Cordis characterized the same change as a “100% variance” (*id.* at PWRAP 003049 SUB; *see also* PX-13 at PWRAP 003009, 0030050, 0030100 SUB). Cordis does not dispute that these statements were intended to have the same meaning. Indeed, at trial, Dr. Buller testified that distinguishing remarks in the ‘762 reexamination file history related to “areas [in the Ersek sleeve] that are twice as thick as other areas, so it’s got a thickness that is twice as thick” (D.I. 1388, 3/8/05 Tr. at 758:8-18; *see also* Tr. 886:1-5).

Cordis’s “nominal thickness” theory – which its experts never adopted and which Cordis affirmatively presented for the first time in its closing arguments – should be rejected.

b. Cordis’s De Minimus Argument Is Contrary To Its Statements During Prosecution

Cordis also appears to argue that because the variation in thickness is limited to about 2 percent of the length of the AVE stent element’s wall, the wall can be of substantially uniform thickness even if two percent of the wall varies in thickness by more than 100% (D.I. 1407 at 10). This theory contradicts the plain language of the Court’s jury instruction for “substantially uniform thickness,” which places no length requirement on the 100 percent variation exclusion (D.I. 1357 at 22-23). Such an argument also is contrary to law.

The Lazarus graft, illustrated below, includes staples 16.



In the “reasons for allowance,” the examiner noted that the presence of this limited area of non-uniformity in wall thickness at one only one end of the graft and distinguished Lazarus because the thickness of the staples precluded the graft from having a “substantially uniform thickness” (PX14, Tab 58 at PWRAP 3259). The PTO found these minimal variations nonetheless precluded a finding of substantially uniform thickness.

Because Cordis did not object to that reason for allowance, it limited the scope of the claims. *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973 (Fed. Cir. 1999); *Inverness Medical Switzerland GmbH v. Warner Lambert Co.*, 309 F.3d 1373, 1380 (Fed Cir. 2002) (“failure to object to an examiner’s interpretation of a claim ordinarily disclaims a broader interpretation”).

Thus, whether or not the variation in thickness occurs over a small fraction of the length of the stent or whether it is near the end of the stent is irrelevant. If some areas of the wall are twice as thick as another – that is, if the variation in wall thickness is 100 percent or more, then the stent cannot infringe.

Cordis fails to address the fact that Cordis never measured any actual stent member (D.I. 1387, 3/7/04 Tr. at 556:15-18; D.I. 1388, 3/8/04 Tr. at 912:22-913:22). At best, Cordis provides only a method of measurement. Theory is not evidence. Cordis then points to AVE documents submitted to the FDA that were created prior to release of commercially available models. Even if these documents have measurements of stent diameter, they do not measure – and were not designed to measure – any variation in thickness in a given stent. Because Cordis failed to provide any evidence of the thickness of the wall of the accused stents, it has not met its burden of proof that the AVE stents have a “substantially uniform thickness.” For this reason as well, the Court should enter judgment as a matter of law that the AVE stents do not infringe.

II. AVE SHOULD BE GRANTED A NEW TRIAL

Cordis approaches its answer to AVE’s new trial brief as it did its closing argument to the jury – without regard for the record.

A. Cordis's Closing Arguments Rewrote The Substantially Uniform Thickness Limitation

Cordis continues in its attempt to inject confusion into the issue of the meaning of the 100 percent variation language in the Court's jury instruction. As described above, the Federal Circuit equated a 100 percent variation in wall thickness with a wall that is twice as thick in some areas as in others. Cordis never disputes this fact.

During its closing arguments, Cordis affirmatively argued for the first time that not all walls that are twice as thick in some areas as in others fall within the 100 percent exclusion. Indeed, Cordis argued to the jury that a 100 percent "deviation" in a stent's wall thickness is mathematically impossible. Incredibly, Cordis contends that this "*misrepresents* Cordis' argument" (D.I. 1407 at 15-16).

The record reveals the truth. Cordis counsel argued that:

- "You can't have a hundred percent deviation" (D.I. 1391, 3/11/05 Tr. at 1767:9-10).
- "It doesn't go down a hundred percent. If it went down a hundred percent, there wouldn't be any stent" (*id.* at 1766:20-1767:2).
- "A variation is a deviation. They're talking about the same thing" (*id.* at 1767:13-14).
- "[AVE's one hundred percent variance test] is a mathematical trick and I think Dr. Wagoner was probably embarrassed by the mathematical trick . . ." (*id.* at 1767:15-17).
- "[Y]ou can't have a negative hundred percent deviation or variation" (*id.* at 1767:20-21).
- "You cannot have a negative deviation of a hundred percent" (*id.* at 1855:9-20).

Despite Cordis's strained attempted to blur the comments made by its counsel during closing, their intent and meaning remain clear. Cordis clings to its sole hope - that it can eviscerate the double thickness/100% variation exclusion.

Cordis's evolving interpretation of the 100% variation exclusion continues with its answering brief. In it, Cordis states that it "agrees that a bent wire stent with a wall thickness ranging from the diameter to two times the diameter, thereby varying upward by 100% of the diameter, would not have a 'substantially uniform thickness'" (D.I. 1407 at 22). Cordis's admission demonstrates the problem with Cordis's new theory – one must determine which diameter is "nominal." In Cordis's example, how

would one know which diameter one should start from? Cordis fails to provide any guidance for this – because there is none available from any source except its own say-so.

More importantly, this position conclusively demonstrates the misleading nature of counsel's closing arguments. Cordis' counsel told the jury that "upward" variations also were impossible (*id.* at 1856:3-10):

What it means is that Dr. Palmaz has staked out a very large football field with his new invention, a negative deviation down can't go a hundred percent, *you can't have a stent that goes up a hundred percent*. If you had a very peculiar wall surface that went up and down a hundred percent, maybe you would be out of his invention, but that's it.

One is rightfully left to ask, what would *not* fit within this football field? Surely Ersek must? And Lazarus? And any and all stents, since apparently it also is impossible to have a stent that has a hundred percent *upward* variation – the only variation that would matter under Cordis's revised claim construction offered in its answering brief.

Cordis did allow during closings that a certain "very peculiar" wall surface "maybe" would fall within the 100 percent variation language – but only if the wall "went up *and* down a hundred percent" (*id.*). In other words, only if the stent varied by as much as 200 percent would it "maybe" fall outside the scope of the invention.

In short, Cordis cannot even make sense out of its closing arguments. Given the emphasis Cordis placed in its closing on its 100 percent variation theory, the argument almost certainly confused the jury. A new trial should be granted for this reason alone.³

B. The Federal Circuit At Least Endorsed One Methodology For
Measuring The Thickness Of A Stent Wall

As explained above, the Federal Circuit defined the "thickness" term in the "substantially uniform thickness" limitation as "equal" to the distance between imaginary circles along the inner and outer surfaces of the stent. *Cordis*, 339 F.3d at 1362. This claim construction is the law of the case, and the

³ Cordis's attempt to characterize its theory as being based in an "admission" by AVE's expert is more than a stretch (D.I. 1407 at 21). The "admission" was an answer based on a question that asked the expert to *assume* that Cordis's incorrect theory was correct (Tr. at 1167:13-1168:1).

jury should have been so instructed. *See, e.g., Sulzer*, 358 F.3d at 1366 (charge should be “adequate to ensure that the jury fully understands the court’s claim construction rulings and what the patentee covered by the claims”); *Choy*, 436 F.2d at 325 (in granting a new trial, Third Circuit finds that district court committed “plain error” in failing to elaborate on abstract instructions so as to put the factual issues in controversy in “their proper perspective”).

However, even assuming, as Cordis contends, that the Federal Circuit’s methodology is one of many possible infringement tests, AVE still was prejudiced. It is undisputed that, *at a minimum*, (i) the Federal Circuit described a methodology for measuring wall thickness in its opinion and (ii) AVE applied that methodology. Regardless whether (as AVE contends) the Federal Circuit set forth that test as the only appropriate test, the endorsement was clear. Yet Cordis was permitted to tell the jury that AVE’s method of identifying the wall surface involved “magic circles,” was a “big trick,” and was a “phony look at the issue” without a curative instruction (D.I. 1391, 3/11/05 Tr. at 1767:23-1768:2; 1770:22-1771:11; 1903:6-1904:1; *see generally* at 1768:1-1771:16).

Cordis was only able to denigrate the Federal Circuit methodology because, prior to trial, the Court had ruled that AVE’s experts could not say that they had relied on the Federal Circuit opinion (D.I. 1329 at 5); and the Court had declined to adopt AVE’s proposed instruction about the use of the circles (D.I. 1319 at 26; D.I. 1357 at 22-23). AVE was further deprived of the ability to point out to the jury, through the testimony of its own witnesses, through cross examination of Cordis’s witnesses, and in closing argument, that the approach used and results obtained by Cordis’s experts were inconsistent with the Federal Circuit’s methodology (D.I. 1337 at 5; D.I. 1319 at 26, § 3.4; D.I. 1304, Tab 2 at 2-3). AVE also had no ability to address Cordis’ theory in AVE’s case in chief, because Cordis did not spring it on AVE until closings.

C. Key Evidence Related To The Clinical Significance Of The AVE Stents Was Excluded From Trial

As discussed above in Section I.B.2.b, Cordis argued to the jury (and continues to do so) that the variation in thickness near the ends of the AVE stents is insignificant (*see, e.g.,* D.I. 1391, 3/11/05 Tr. at

1765:10-1768:17). The Court restricted AVE from presenting key evidence that variations in thickness near the ends of the AVE stents are clinically significant (D.I. 1390, 3/10/05 Tr. at 1513:17-24; D.I. 1337 at 8-9, §§ 4(k) & 4(m); *see also* D.I. 1337 at 7-8, §§ 4(h)-4(j)).⁴ The clinical significance of the tapered crowns is relevant because would have further supported AVE's contention that the variable thickness is "substantial."

The cases cited by Cordis are inapposite. They stand for the proposition that where the accused device includes all of the claim limitations, infringement cannot be avoided merely because of improvements to the claimed invention. But here, the issue is whether one of the claim limitations – the "substantially uniform thickness" limitation – is present in the accused device. How the AVE stents function in the body is directly relevant to this issue.

Cordis takes the position that because two engineers testified tangentially about clinical matters there is no error. However, the expert AVE proffered on clinical issues, Dr. Heuser, was not allowed to testify as to that issue (D.I. 1305, Ex. H, 10/29/04 Heuser Rpt at ¶¶ 22, 25, 28, 30, 31). It was Dr. Heuser, AVE's sole cardiologist at trial, who could have offered the most detailed and informative testimony about the clinical benefits of the tapered crowns. When the witness offered by a party as the medical authority fails to speak to an issue that is important, that silence becomes negative testimony in its own right. AVE was also effectively precluded from playing the Schatz video, which would have provided evidence of the clinical significance of the mass uniform thickness of Medtronic's stents. (D.I. 1337 at ¶4k). Indeed, the believability of Dr. Wagoner and Mr. Allen, on this point and more broadly, was called into question because AVE's medical expert in the field was silenced.

Because this relevant clinical evidence almost certainly would have influenced the jury's infringement analysis, a new trial should be granted. *See Petree v. Victor Fluid Power, Inc.*, 887 F.2d 34,

⁴ Cordis incorrectly argues that the Court's March 1, 2005 Order (D.I. 1337 at 8) precluded AVE from offering any evidence as to the clinical significance of the AVE stents. The Court's Order precluded AVE from offering evidence to prove that the AVE stents were improvements over the claimed inventions – *i.e.*, it prevented a subset of the clinical significance evidence from coming into evidence. At trial, the Court prevented AVE's key witness on the issue from presenting any testimony as to the broader issue of clinical significance (D.I. 1390, 3/10/05 Tr. at 1513:17-24).

41 (3d Cir. 1989) (exclusion of evidence is “harmless only if it is highly probable that the error did not affect the outcome of the case”).

D. Cordis Was Improperly Allowed To Elicit Irrelevant And Highly Prejudicial Testimony

Cordis violated the letter and spirit of the Court’s *in limine* ruling when it elicited testimony and argued during closing that neither AVE, Dr. Palmaz, Dr. Gianturco, nor others personally came up with the idea claimed in the ‘984 patent (*see, e.g.*, D.I. 1390, 3/10/05 Tr. at 1508:21-1509:8; D.I. 1388, 3/8/05 Tr. at 823:6-19, and at 828:19-829:8).

Cordis misstates the record and the law in its response. First, it argues that the Court’s *in limine* ruling was limited to Dr. van Breda because AVE’s motion “was *explicitly* directed at” Dr. van Breda (D.I. 1407 at 29 (emphasis added)). AVE’s motion was neither explicitly nor impliedly so limited. Indeed, AVE’s motion *in limine* was entitled as a motion to preclude “Cordis from Offering Evidence, Argument, Or Testimony as to whether Any Witness Thought of the Apparatus Claimed in the Cordis Patents” (D.I. 1304, Tab 8 at 1). AVE repeated this statement in the introductory and closing statements of the motion. While AVE did refer to Cordis’s use of Dr. van Breda’s testimony from the first trial as an example of the type of argument that should be precluded, that is because Dr. van Breda was AVE’s only testifying obviousness expert from that trial. Moreover, the Court explicitly stated in its Order granting the motion that Cordis was not to introduce “evidence, argument, or testimony as to whether *any* witness thought of the apparatus claimed in the Cordis patents” (D.I. 1337 at 12).⁵

Cordis’s second argument, that the evidence is a probative of nonobviousness, is a slight of hand. Cordis is correct that (1) where one of skill in the art states that the solution chosen by the patentee will not work, and (2) that person chooses a different route, then the evidence is relevant to nonobviousness. However, here Cordis relied upon the fact that Dr. Gianturco, AVE, and others personally chose to go a different direction than the patented invention. Cordis submitted *no* evidence that these entities believed

⁵ Cordis’s argument is puzzling for an additional reason. Dr. van Breda, while an outstanding doctor, does not hold a special place in the law. What applies to Dr. van Breda should have applied to all experts and other witnesses.

that the use of a single connector (the Schatz '984 patent) *would not work*. Cordis's evidence thus is irrelevant. *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004); *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1364 (Fed. Cir. 2001).

E. Cordis Fails To Respond To Its Counsel's Most Egregious Statements

In its New Trial brief, AVE provided the Court with what Cordis terms a "laundry list" of quotes questioning AVE's motives in defending the suit and the integrity of Dr. Ersek, Mr. Hammerslag, and even of Cordis (before Cordis was purchased by Johnson & Johnson).

Cordis does not deny that most of the arguments it made were irrelevant. Indeed, it does not even dispute that some are prejudicial. For example, Cordis does not even make an attempt to justify its plea to the jury to find for Dr. Palmaz because the '762 is about to expire (D.I. 1398 at 22). As AVE explained, this argument is irrelevant, a call to pure emotion, and misleading (*id.* at 22-23).

Cordis also does not attempt to justify its repeated argument that AVE does "things the wrong way," that its motivation was to avoid paying Cordis money, and that Cordis offered, and AVE refused, to pay it money. Again, these arguments are all irrelevant, a call to pure emotion, and misleading. Indeed, in Cordis's motion in limine in 2000 to prohibit AVE from referring to Cordis's request for injunctive relief, Cordis argued that any references to a potential injunction would engender "unfair prejudice" (D.I. 836, Tab 1 at 2-3). Discussion of the other available remedy (money damages) during the liability phase is similarly prejudicial. *Smith-Walker v. Zielinski*, 2003 U.S. Dist. LEXIS 9078, 14-15 (D. Ind. 2003) (finding that any mention of damages during liability phase of bifurcated civil injury trial would be prejudicial).

These and other arguments also are without any evidentiary support. Cordis's claims to the contrary are incorrect:

1. Cordis's counsel said at trial "[AVE] would rather invest in a litigation than invest in paying for the right to use the technology" (D.I. 1391, 3/11/05 Tr. at 1885:14-22). Cordis never sought nor elicited any such testimony from Jeff Allen, AVE's representative, or any other witness. Nor did it

introduce any documentary evidence supporting this factual assertion. Certainly Bob Croce, a former Cordis executive, is incapable of testifying regarding AVE's intent.

2. Cordis's counsel said during closing "[Cordis] licensed the Hammerslag *nutty* idea, the liner made from an unimaginable substance based on no idea useful in the treatment of restenosis *in the theory that it would give them some position in the stent patent fights*" (D.I. 1391, 3/11/05 Tr. at 1886:15-24). Not surprisingly, Cordis can find no support for the most damaging part of this statement, that the license of the Hammerslag patent was not for its merits, but for litigation purposes. These facts were not in evidence and would be highly probative to the weight a jury gave the actual testimony that was elicited – that Cordis had agreed with Dr. Hammerslag that his patent covered all balloon expandable stents. Absent evidence to counter this fact, Cordis's counsel fabricated the evidence needed.

3. Cordis has failed to find any support for its claim that Dr. Ersek is "delusional." To tell a jury that a key defense witness is, in effect, mentally disabled without any support is highly prejudicial.

4. Finally, Cordis's counsel told the jury that Dr. Ersek was paid \$540,000 by Medtronic, Inc. and that this is the "ugly side of some parts of corporate America" (D.I. 1391, 3/11/05 Tr. at 1890:19-23). This was, in fact, an outright falsehood. Cordis's counsel knew well from review of Dr. Ersek's consulting agreement and from the testimony elicited at trial that the amount paid to Dr. Ersek was nowhere near \$540,000 (D.I. 1389, 3/9/05 Tr. at 255:1-20; D.I. 1390, 3/10/05 Tr. at 1344:19-1346:5). In addition, by ruling that Dr. Ersek's consulting agreement could not come into evidence, the Court prevented the jury from seeing physical evidence that would support the testimony from the "delusional" Dr. Ersek that he was not making \$540,000 under that agreement and that he was not hired for some "ugly" purpose. Certainly this was a case where counsel was asking the jury "ignore [the] facts." *Intel Corp. v. Broadcom Corp.*, 2003 WL 360256, at *26-27 (D. Del. Feb. 13, 2003).

Cordis's repeated reliance during its closing on irrelevant and prejudicial statements – most of which have no support in the record – leaves no doubt that the verdict was influenced by the prejudicial statements.⁶ *Blanche*, 57 F.3d at 264. A new trial should be granted on all issues.

F. Cordis Relied On The AVE Stent For Secondary Considerations
Of Nonobviousness

Cordis does not seriously dispute that, as a result of its representation that it would not rely on AVE's stents (or any stents other than its own) for secondary considerations, the Court excluded some of the most powerful evidence in rebuttal to Cordis's sweeping statements about the entire stent industry adopting the Palmaz design. Instead, Cordis selectively cites to portions of the record in an effort to argue that AVE overstates the prejudice.

Cordis first argues that it “did not ‘open the door’” to allow AVE to put on the rebuttal evidence (D.I. 1407 at 26). It argues that that it did not argue that the industry “copied” the AVE design, and did not rely on AVE for commercial success. As an initial matter, the record overwhelmingly demonstrates that Cordis relied on AVE's success in support of commercial success (D.I. 1398 at 23-28).⁷ Most importantly, Cordis admitted in its May 6 brief that it relied on the “entire industry” (which obviously includes the AVE stents) to prove the “legitimate secondary consideration reflecting praise for, and acceptance of, Dr. Palmaz's invention” (D.I. 1345 at 4-5 (cited in D.I. 1398 at 27, 29)).

Cordis conveniently ignores this secondary consideration in its brief. It does so for good reason: Cordis represented to the Court that it would not rely upon the AVE stents for secondary considerations; yet Cordis admittedly relied on the AVE success in support of the secondary consideration of praise for, and acceptance of, Dr. Palmaz's invention; AVE was not permitted to rebut this secondary consideration

⁶ Cordis also failed to respond to AVE's argument that a new trial is warranted on the basis of Cordis's equating the patent claims to the balloon expandable stent (*see, e.g.*, D.I. 1386, 3/4/05 Tr. at 119:16-20, 120:7-8, 121:24-122:3, 126:18-127:4, 128:18-20; 132:24-133:5, and 144:20-145:14; *see also* PX-3 claim 23; PX-6, claims 1 and 3). Claim 23 of the '762 patent, and claims 1 and 3 of the '984 patent, do not even claim a balloon expandable stent.

⁷ Cordis's distinction of *Stratoflex* based on the limited number of actors is curious given that, at the time of the alleged infringement, there were only between two and four participants in the entire coronary stent field.

with its most powerful evidence; and the jury was instructed that it could consider this secondary consideration (D.I. 1386, 3/4/05 Tr. at 216:9-13; D.I. 1398 at 23-28; D.I. 1357 at 32-33).

Indeed, despite Cordis's contention that it did not rely on the AVE (or any other) stents at trial to establish commercial success – Cordis did just that. Indeed, while Cordis denies that fact for purposes of this motion, in its Opening Brief In Support of Cordis's Motion To Reinstate And Update The Damages Verdict Against BSC and AVE filed April 19, 2005, Cordis argued that it presented evidence that the ACS Multilink stent infringed, which purportedly “neither defendant contested.”⁸ (D.I. 1394 at 3). Cordis argued that “[i]n the AVE trial, Cordis proved that the ACS stents, *along with the other market leaders*, combined the three principal ideas of Dr. Palmaz - a first diameter for intraluminal delivery, a second diameter that is variable and deformed upon the application of force, and a tubular member with longitudinal slots” (*id.* at 3 (citing Buller 3/8/05 Tr. (D.I. 1388) at 720-721; Heuser 3/10/05 Tr. (D.I. 1390) at 1572)). The only other market leader (in fact one of the only two other companies with a stent on the market) was AVE (Tr. 1072:21-1075:7). Cordis's transcript citations apply equally to AVE and clearly were used to establish commercial success – not simply as embodiments as Cordis would suggest (Buller 3/8/05 Tr. (D.I. 1388) at 720-21):

- Q. Dr. Buller, I'd like to ask you, taking these three elements together, is that -- that is, "tubular member with longitudinal slots, that has a first diameter for intraluminal delivery, and a second diameter that is variable and deformed upon the application of force." I'd like to ask you your opinion, if any, about the connection between those three elements which I've summarized and we've reviewed in detail and today's stent industry?
- A. These -- *these are the critical things which have led to this enormous multi-billion dollar industry* that exists today. These are the things that allow this phenomenal controllability as well as the required lateral scaffolding that allows us to have the very, very useful and life-saving devices that we have today.

It is disingenuous for Cordis to argue in one brief that it established that other stents were embodiments, while arguing here that it did no such thing.

⁸ Of course, Cordis does not explain why defendants had to contest evidence that Cordis represented it would not offer.

Cordis's final argument is that it "is disingenuous" of AVE to argue that it was "precluded from offering evidence showing that AVE's success was due to features not covered by the asserted patent claims" (D.I. 1407 at 27). According to Cordis, AVE's witnesses testified "at length" about how the tapered crowns are a critical design feature, and about how Medtronic has patents (*id.* at 27-28). Cordis again mischaracterizes the record. The "at length" testimony amounts to a few lines. Moreover, the evidence AVE was precluded from presenting was not limited to the tapered crowns. In order to rebut the nexus, AVE should have been permitted to point to *any* patented or unpatented features of its stents as the reason for its success. AVE was not permitted to present this evidence.

G. A New Trial Should Be Granted Because The Jury's
Infringement And Non-Obviousness Verdicts Are Not Supported
By the Weight Of The Evidence

As set forth in AVE's JMOL and New Trial Briefs as well as this brief, Cordis provides no relevant evidence that would rebut the fact that the verdict of infringement is against the weight of evidence. Moreover, a new trial on infringement is particularly appropriate here, where, as described above, Cordis relied upon several irrelevant and prejudicial arguments in support of its case and cannot rebut those arguments. *Roebuck v. Drexel Univ.*, 852 F.2d 715, 737 (3d Cir. 1988).

Cordis also responds to AVE's arguments that the verdict of non-obviousness is against the weight of the evidence by putting forward irrelevant and prejudicial arguments. AVE's detailed obviousness analysis with respect to the '762 and '984 patents has not been rebutted (*see, e.g.*, D.I. 1389, 3/9/05 Tr. at 1209:11-1258:22 (Dr. Ersek); D.I. 1390, 3/10/05 Tr. at 1367:3-1384:8 and 1414:17-11425:11 (Dr. Piehler), at 1426:20-1474:22 (Dr. van Breda), at 1524:4-1566:3 and 1615:23-1620:24 (Dr. Heuser)). Cordis's arguments were constructed from irrelevant opinion and secondary considerations for which no connection to the claims at issue were established. The great weight of the material evidence supports AVE. A new trial should be granted.

In addition, if Cordis's new revision of the substantially uniform thickness limitation is to be accepted by this Court, then it would place the Ersek and Lazarus references in an entirely different light.

Under Cordis's theory, it is entirely possible the Ersek device, without modification, would meet the substantially uniform thickness limitation.

CONCLUSION

For the foregoing reasons, AVE's motions for JMOL and New Trial should be granted.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on May 19, 2005 I electronically filed Medtronic Vascular Inc.'s Combined Reply Brief In Support Of Its Motion For Judgment As A Matter Of Law On Cordis Corporation's Patent Infringement Claims And Its Motion For A New Trial with the Clerk of the Court using CM/ECF which will send notification of such filing by email to Steven J. Balick at sbalick@ashby-geddes.com and to Josy W. Ingersoll at jingersoll@ycst.com.

I also hereby certify that I caused copies to be served on May 19th, 2005 upon the following counsel of record in the manner indicated:

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